

REMARKS

Claims 1-40 were presented in the original application. In response to the Restriction Requirement in the Office Action dated April 8, 2008, Applicant elected the Group 1 claims without traverse, and canceled claims 18 and 20 of the non-elected Group II invention without prejudice. In the Office Action dated September 15, 2008, the Examiner vacated the previous Restriction Requirement and provided a substitute Restriction Requirement. Claims 1, 12, 19, 26-33 are currently amended. Support for the claim amendments can at least be found in the Specification as originally filed on Page 21, lines 4-7 and original claims 21 and 23. Claim 13 has been canceled. Support for the amendment to claim 36 (i.e. *ΔhcsEFG2319*) can at least be found in Table 2 on page 28 and on page 64. The amendment of claim 3 is simply to conform the language in the claim to the nomenclature used in the specification.

PATENT TERM ADJUSTMENTS UNDER 35 USC §154 AND 37 CFR §1.703.

Applicants respectfully submit that the entire delay in prosecution extending from the Applicants response of May 7, 2008 in good faith to the original Restriction of April 8, 2008 until the USPTO mailing of the Action of September 15, 2008 vacating that original Restriction and imposing a new Restriction constitutes a delay in prosecution by the Office. Applicants therefore respectfully request that this delay extending from May 7, 2008 to September 15, 2008 be properly accounted for in any subsequent calculations of Patent Term pursuant to 35 USC §154 and 37 CFR §1.703 that are applicable.

ELECTION/RESTRICTIONS

In the Restriction Requirement dated September 15, 2008, the Examiner alleged that the pending claims encompass three groups of Inventions that allegedly “are not so linked as to form a single general inventive concept under PCT Rule 13.1”:

Group I. Claims 1-10, 12-16, 19, 21-26, and 32-40, drawn to a live attenuated derivative of a pathogenic *Salmonella* species consisting essentially of (a) a means for regulatable expression of

a gene that encodes a regulatory protein, wherein non-expression of said regulatory protein in vivo causes synthesis of a first antigen that is conserved among *Salmonella* species and *E. coli* strains; and (b) a means for regulatable synthesis of a first carbohydrate antigen, wherein said first carbohydrate antigen ceases to be synthesized in vivo, exposing a second carbohydrate antigen that is conserved among *Salmonella* species and *E. coli* strains; wherein said attenuated derivative has enhanced ability to induce cross-protective immunity against *Salmonella* species and *E. coli* strains, a live attenuated derivative of a pathogenic *Salmonella* species, and vaccine.

Group II. Claims 11 and 17, drawn to a method for inducing an immune response sufficient for protection against infection by *Salmonella* species and *E. coli* strains and a method of inducing a cross-protective immune response against *Salmonella* species.

Group III. Claims 27-31, drawn to a recombinant bacterial strain consisting essentially of a means of regulatable expression of a virulence gene.

Applicants hereby provisionally elect *with traverse* the Group I invention, which is, as currently amended, drawn to a live attenuated derivative of a pathogenic *Salmonella* species consisting essentially of (a) a means for regulatable expression of a *fur* gene that encodes a regulatory protein, wherein said gene is expressed when said attenuated strain is in the intestinal tract of an individual and said gene is not expressed when said attenuated strain is within internal tissues of an individual and wherein non-expression of said regulatory protein in vivo causes synthesis of a first antigen that is conserved among *Salmonella* species and *E. coli* strains and (b) a means for regulatable synthesis of a first carbohydrate antigen, wherein said first carbohydrate antigen ceases to be synthesized in vivo, exposing a second carbohydrate antigen that is conserved among *Salmonella* species and *E. coli* strains; wherein said attenuated derivative has enhanced ability to induce cross-protective immunity against *Salmonella* species and *E. coli* strains, a live attenuated derivative of a pathogenic *Salmonella* species, and vaccine. Applicants identify claims 1-10, 12-16, 19, and 21-26, and 32-40 as the claims corresponding to this election.

All of the currently pending claims as amended now either include, depend from a claim including, or otherwise incorporate some form of the amended language of claim 1: “wherein a regulatable promotor is operably linked to said gene, wherein said gene is expressed when said attenuated strain is in the intestinal tract of an individual and said gene is not expressed when said attenuated strain is within internal tissues of an individual...” The Examiner alleged that the special technical feature of the previously pending Group I claims (i.e. essentially the previously pending claim 1) is *prima facie* obvious and unpatentable over Roy et al., WO 2001/83785A2 dated November 8, 2001 in view of Roy et al., US Patent Number 6,024,961 dated February 15, 2000. Therefore, the Examiner alleged that “Group I lacks unity with Groups II-III because the technical feature of Group I is anticipated by the art and therefore not ‘special’ within the meaning of PCT Rule 13.2 because it does not provide for a contribution that the claimed invention makes over the art.”

Applicant respectfully note that all the pending claims as currently amended now incorporate the feature that the regulatable *fur* gene is expressed when the attenuated strain is in the intestinal tract of an individual and the gene is not expressed when the attenuated strain is within internal tissues. Neither WO 2001/83785A2 or US Patent Number 6,024,961 teach or suggest this feature. Therefore, Applicant respectfully asserts that the Examiner’s allegation of obviousness has been rebutted. Because all of the pending claims as currently amended now incorporate a special technical feature that is not known in the art, the currently pending claims are linked as to form a single general inventive concept under PCT Rule 13.1, and Applicant respectfully asserts that the Examiner’s Restriction Requirement has been properly and adequately traversed and requests that the Examiner withdraw the current Restriction Requirement between Groups I, II, and III.

ELECTION OF SPECIES

Applicant hereby elects *without* traverse the following species for the purposes of examination. From the Group I list of Species A-regulatory protein Applicant elects Species 1-*fur*. From the Group I list of Species B-mutation Applicant elects Species 1- $\Delta(gmd-fcl)$ -26. In

claim 37, this election corresponds to the claimed “gmd” element. Should the Examiner reconsider the Restriction of the alleged Groups I, II, and III claims, Applicant further elects the species 7 “regulatory protein” “crp” for purposes of examination as per the list provided on Pages 5 to 6 of the September 15th Restriction as “Species Group II a) Species A-regulatory protein”. Applicants note that this list provided by the Examiner apparently refers to various virulence gene species recited in currently pending claim 28.

AMENDMENTS TO THE CLAIMS

Claims 1 and 33, have been amended to add the language “wherein a regulatable promotor is operably linked to said gene, wherein said gene is expressed when said attenuated strain is in the intestinal tract of an individual and said gene is not expressed when said attenuated strain is within internal tissues of an individual....” Likewise, claims 12 and 19 have been amended to add the similar language “wherein the fur promotor is replaced with a regulatable promotor operably linked to said fur gene, wherein said fur gene is expressed when said attenuated strain is in the intestinal tract of an individual and said fur gene is not expressed when said attenuated strain is within internal tissues of an individual” and “wherein said fur gene is expressed when said attenuated strain is in the intestinal tract of an individual and said fur gene is not expressed when said attenuated strain is within internal tissues of an individual...” respectively. Applicants believe that all of the currently pending claims now either contain or incorporate the feature that the regulatable gene expression occurs in the intestinal tract but not within internal tissues of an individual. Support for these amendments can at least be found in the Specification as originally filed on Page 21, lines 4-7 and original claims 21 and 23.

Claim 13 has been canceled.

Claim 26 -32 have been amended to depend from or otherwise incorporate the features of claim 1.

CONCLUSION

It is not believed that extensions of time are required beyond those which may otherwise be provided for in this filing. In the event however that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned for under 37 C.F.R. §1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account 20-0823.

The Examiner is encouraged to contact the undersigned via telephone at the number provided, if it is determined that personal communication will expedite prosecution of this application.

Respectfully submitted,



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